

AMENDMENTS TO THE CLAIMS

1. – 49. (Cancelled)

50. (New) A process for the preparation of concentrated, sterile injectable solutions containing, as active pharmaceutical ingredient(s) (API), a taxane derivative, docetaxel (2R,3S) 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7- β -10- β -tri-hidroxy-9-oxo-tax-11-en-13 α -yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate (I), or paclitaxel, 4-acetoxy-2- α -benzoyloxy-5- β -20-epoxy-1,7 β -10- β -tri-hidroxy-9-oxo-tax-11-en-13 α -yl (2R,3S) 3-benzoylamino-2-hydroxy-3-phenylpropionate (II), comprising the following steps:

- (a) Adding docetaxel or paclitaxel, having a water content of lower than 1.0% w/w, to a biocompatible vehicle or excipient having a pH in the range of 3.0 to 6.5 and optionally comprising a non-nucleophilic antioxidant, at a temperature of 20 to 40 °C, until the docetaxel or paclitaxel is completely solubilized and forms a transparent solution, in which the concentration of the active principle in the vehicle or excipient is in the range from 1 to 100 mg/mL;
- (b) Filtering the solution obtained in (a) by passage through a sterilizing membrane having pores less than or equal to 0.45 μ m.

51. (New) The process according to claim 50 further comprising the following steps to obtain the docetaxel (I) or paclitaxel (II) having a water content of less than 1.0% w/w:

- (i) Solubilizing the respective hydrated forms of doclitaxel or paclitaxel in a solvent or in a chemically inert solvent mixture which forms an azeotrope with water and of sufficient polarity to completely solubilize the docetaxel or paclitaxel, wherein the solution has a concentration range between 1 - 100 mg of the docetaxel or paclitaxel to 1 mL of the solvent or solvent mixture;
- (ii) Removing the water in the mixture (i) by azeotropic distillation at a temperature between -20 and 200 °C and at a pressure in the range of 0.001 and 780 mm Hg, until the water content is lower than 1.0% w/w.

52. (New) The process according to claim 51 wherein the solvent of step (i) is an anhydrous solvent or a mixture of solvents.

53. (New) The process according to claim 52 wherein the anhydrous solvent is an alcohol, an aliphatic or cyclic ether, an organic acid, a halogenated solvent or an aromatic solvent.

54. (New) The process according to claim 53 wherein the solvent is a linear or branched chain biocompatible alcohol.

55. (New) The process according to claim 54 wherein the alcohol employed is ethanol.

56. (New) The process according to claim 51 wherein the hydrated docetaxel or paclitaxel is hydrated with 1.1 to 20.0% w/w of water, the solvents of step (i) consist of absolute ethanol and anhydrous toluene in a relative proportion of 1:9, and step (ii) is performed at a temperature between 10 and 70 °C and at a pressure between 10 and 100 mm Hg.

57. (New) The process according to claim 56 wherein the docetaxel or paclitaxel is hydrated with 1.1 to 4.9% w/w of water.

58. (New) The process according to claim 51 wherein the active principle employed as raw material in step (i) is docetaxel trihydrate, (2R,3S) 4-acetoxy-2- α -benzoyloxy-5 β -20-epoxy-1,7- β -10- β -tri-hidroxy-9-oxo-tax-11-en-13 α -yl 3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate 3 H₂O, (III), in which the water content is 5.0 to 6.8% w/w.

59. (New) The process according to claim 51 wherein the raw material employed in the step (i) comprises hydrated paclitaxel derivatives.

60. (New) The process according to claim 50 wherein the vehicle is polysorbate 80 and the concentration range of docetaxel, on an anhydrous basis, is from 20 to 60 mg/mL, and the sterilizing membrane employed in the filtration step has a pore size of 0.22 μ m.

61. (New) The process according to claim 50 wherein the vehicle is polysorbate 80 and the concentration range of paclitaxel on an anhydrous basis is from 10 to 100 mg/mL, and the sterilizing membrane described in the filtration step has a pore size of 0.22 μm .

62. (New) The process according to claim 50 wherein the vehicle comprises at least one polyethoxylated sorbitol.

63. (New) The process according to claim 62 wherein the polyethoxylated sorbitol is polysorbate 80.

64. (New) The process according to claim 50 characterized in that the acid added to the active ingredient is pharmaceutically compatible and the vehicle or excipient used includes the non-nucleophilic antioxidant.

65. (New) The process according to claim 50, wherein the acid is vehicle or excipient comprises an acid selected from the group consisting of ascorbic, phosphoric, acetic, citric and tartaric acids and mixtures thereof.

66. (New) The process according to claim 65 wherein the vehicle or excipient is polysorbate 80 and the non-nucleophilic antioxidant is present and selected from the group consisting of acetic, citric and ascorbic acids, or a combination thereof, in such quantity as to adjust the pH of the resultant filtered solution in the range of 3.0 to 4.5.